III. Summary of Safety and Effectiveness

A. Applicant

Name:	MedCom GmbH
Address:	12 Rundeturmstrasse Darmstadt, HE 64283 Germany

B. Device

Trade name:	VeriSuite
Common name	Patient position verification system
Classification name:	System, Radiation Therapy,Charged-Particle, Medical
Classification Number:	892.5050
Classification:	Class II
Product code:	LHN

C. Device Trade Name

VeriSuite also marketed as
VeriSuite 1.6 and
VeriSuite-Particle and
VeriSuite-Particle 1.6

D. Predicate device

Device trade name:	EXACTRAC 5.5 / ExacTrac X-RAY 6D
510(k) number:	K072506
Company name:	BRAINLAB AG
Classification Number:	892.5050
Classification:	Class II
Product code:	LHN

X-Ray Generator, Sedecal SHF 835

Device trade name:	
Classification name:	Generator, High Voltage Xray, Diagnostic
Classification Number:	892.1700
Classification:	Class I Exempt
Product Code:	IZO
Manufacturer Registration Number:	9617251

X-Ray Tubes, Varian A277 / A272

Classification name:	Assembly, Tube, Housing X-ray, Diagnostic
Classification Number:	892.1700
Classification:	Class I Exempt
Product Code:	IZO
Manufacturer Registration Number:	1717855

Flat Panel Digital Imager, Varian PaxScan 4030R

Classification name:	Solid State X-ray Imager
Classification Number:	892.1630
Classification:	Class II
Product Code:	MQB
510(k) Number:	K024147

Collimator, Ralco 302

Classification name:	Device, Beam Limiting, X-ray Solid State X-ray Imager
Classification Number:	892.1610
Classification:	Class II
Product Code:	KPW
510(k) Number:	K946320

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2008

Mr. Stefan Walter
Quality Manager
MedCom GmbH
12 Rundeturmstrasse
Darmstadt, HE 64283
GERMANY

Re: K080742
Trade/Device Name: VeriSuite
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: March 14, 2008
Received: March 17, 2008

Dear Mr. Walter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

VIII. Indications for Use Statement

510(k) Number (if known): K080742

Device Name: VeriSuite

The VeriSuite patient position verification system is used for verification and correction of the patient's position during a radiotherapy treatment with external beams or charged particles. It is based on stereoscopic X-ray images and DRRs calculated from a CT image series of the treatment region of the patient and information from the treatment planning.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080742